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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/870,009

Filing Date: May 30, 2001

Appellant(s): KASHIMA ET AL.

**MAILED** 

SEP 0 8 2006

**GROUP 1600** 

Phillip E. Miller For Appellants

**EXAMINER'S ANSWER** 

This is in response to the appeal brief filed 6/26/06 appealing from the Office action mailed 1/24/06.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in

the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

In addition to the grounds of rejection, set forth by appellants in the Brief, to be reviewed on appeal, the following new grounds of rejection are also to be reviewed.

#### **NEW GROUND(S) OF REJECTION**

# Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5, 8-12, 15, 17-27, and 30-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 5, 8-12, 15, 17-27, and 30-34 are rejected under 35 U.S.C. 101 because they encompass viral genomes comprising LTRs (long terminal repeats). In addition, any animal or person infected with such a virus inherently encompasses the LTRs, thus the cells recited in the instant claims encompass humans and animals. As the DNA and cells recited in the instant claims are not limited to be different from those existing in nature; i.e. they are not limited to be "purified" or "isolated," claims 5, 8-12, 15, 17-27, and 30-34 encompass naturally existing organisms and humans, and are thus directed to nonstatutory subject matter.

### (7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

#### (8) Evidence Relied Upon

5,854,033 LIZARDI 12-1998

Arnot et al. "Digital codes from hypervariable tandemly repeated DNA sequences in the Plasmodium falciparum circumsporozoite gene can genetically barcode isolates." Molecular and Biochemical Parasitology, Volume 61, (1993), pages 15-24.

"embed" definition. Merriam-Webster online dictionary, 2005, on the world wide web at http://www.m-w.com/dictionary/embed, 2 pages.

### (9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

#### Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5, 8-12, 15, 17-27, and 30-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 5, 8-12, 15, 17-27, and 30-34 are rejected under 35 U.S.C. 101 because they encompass viral genomes comprising LTRs (long terminal repeats). In addition, any animal or person infected with such a virus inherently encompasses the LTRs, thus the cells recited in the instant claims encompass humans and animals. As the DNA and cells recited in the instant claims are not limited to be different from those existing in nature; i.e. they are not limited to be "purified" or "isolated," claims 5, 8-12, 15, 17-27, and 30-34 encompass naturally existing organisms and humans, and are thus directed to nonstatutory subject matter.

# Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### **NEW MATTER**

Claim 32 recites a "portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence" which is not supported by the specification, claims, and drawings, as originally filed. While the original claim 1 recites "portion of said DNA other than a gene", there is a lack of written support for the limitation that the "other portion" NOT include a protein code sequence and transcription control information. Page 13 (lines 3-6) of the specification states: "a gene portion wherein a protein code sequence and its transcription control information are stored, and a portion wherein genetic information is not included" (emphasis added by examiner). While the specification discloses what that the "gene portion" includes, this disclosure fails to teach what the "other" portion does NOT include. In addition, "genetic information" and "protein code sequence and its transcription code information" differ in scope. Original claim 5 recited DA comprising "a portion, other than said gene portion, including no genetic information." This does not provide support for a portion which is specifically limited to

Page 6

Art Unit: 1631

"not store a protein code sequence and transcription control information" as currently recited in the claims. Original Figures 1 and 3 merely show a "portion other than gene" and thus do not support the newly added limitation. Because the introduction of the phrase "portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence" does not have support in the specification, claims, or drawings, as originally filed, this phrase is considered to be NEW MATTER.

# Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the phrase "intentionally designed" which is vague and indefinite. It is unclear what limitation of a nucleic acid or structure is intended by the recitation that it be "intentionally designed". In addition, it is unclear what is considered to be an "unintentionally designed" nucleic acid. Claims 9-10 are also rejected due to their dependency from claim 8.

Application/Control Number: 09/870,009 Page 7

Art Unit: 1631

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 8-12, 15, 17-27, and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lizardi (US 5,854,033).

Lizardi discloses detecting mutations in target sequence genes; for example, the identified gene responsible for Huntington's chorea, by designing an open circle probe (col. 22, lines 20-37), Figure 1 shows a open circle probe hybridized to a target sequence, and Figure 5 shows an open circle probe with detection tags which represents a first gene portion including a predetermined gene for Huntington's chorea, a second portion which is other than said gene portion (=probe), and a not naturally occurring nucleotide sequence (=detection tag) which is embedded in a portion other than said gene portion and comprises source identification information of said predetermined gene, as stated in instant claims 5, 8, 11, 12, 15, and 27.

Lizardi discloses DNA ligation which circularizes a specially designed nucleic acid probe used to detect the presence of specific nucleic acids in a sample (abstract) containing the detection tags (Figure 5) which represents a special sequence that is intentionally designed and included as part of the nucleotide sequence, as stated in instant claim 8. Figure 5 shows multiple detection tags, a primer complement, a promoter, and target probes which represent at least one special sequence with a plurality of sequences having a plurality of types of patterns (=different

sequence patterns) embedded at predetermined locations of DNA, as stated in instant claims 9, 10, and 18-20. Lizardi discloses in situ hybridization in cytogenetics (col. 23, lines 1-10) which encompasses a cell of an organism, as stated in instant claim 12. Lizardi discloses detecting various mutant genes (Examples 2 and 3) which represent a value-added gene that is provided by gene manipulation, as stated in instant claim 17. Lizardi discloses copies of the open circle probe in Figure 11b which represents copy tolerance, as stated in instant claim 21. Lizardi discloses the detection tag portions of the open circle probe may have 60 tag portions or less with same or different sequences which can be any length that supports specific and stable hybridization between tags and the probes (col. 7, lines 6-31) which represents embedding at random locations as well as watermark (=specific sequences), as stated in instant claims 22 and 30. The detection portion of the open circle probe is separate from the target sequence containing the gene (Figure 5 and 8) which represents the at least one nucleotide sequence is not naturally generated through gene mutation, as stated in instant claim 23. Lizardi discloses using enzyme-linked detection systems (abstract) and Figure 5 shows the promoter of the open circle probe, as stated in instant claim 24. Lizardi discloses if any target sequences are present then the open circle probe ligates to it and detection tags allow for detection (col. 22, lines 37-49) which represents detecting a complementary sequence, as stated in instant claim 25. Figure 5 gives an example of detection tags being embedded at predetermined locations, as stated in instant claim 26. The genes in Examples 2 and 3 represent protein code sequence and Figure 8 shows transcriptional initiation sites, as stated in instant claim 31. Figure 5 shows detection tag portions which represent a portion which is other than said gene portion that does not store protein code sequence and transcriptional control information, as stated in instant claim 32.

Page 9

Figure 10 shows amplified RNA which represents a gene portion transcribed into RNA and a portion other than said gene portion which is not transcribed, as stated in instant claim 34. Lizardi discloses using oligonucleotides for wild type and mutant gene detection via ligation (col. 36, line 19 to col. 37, line 20 and col. 38, line 48 to col. 39, line 67) which represents producing a gene by artificial, intentional manipulation, as stated in instant claim 33. Lizardi discloses including a unique address tag within the spacer region of the open circle probe so that tandem sequence DNA generated from a given open circle probe will contain sequences corresponding to a specific address tag sequence (col. 22, lines 13-18).

Thus, Lizardi anticipates the instant invention.

Claims 5, 8-11, 15, 17-27, 30, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnot et al. (Molecular and Biochemical Parasitology, Volume 61, 1993) with additional support from Merriam-Webster online dictionary ("embed" definition).

Arnot et al. disclose genomic DNA including the CS gene of Plasmodium falciparum (abstract and page 17, col. 1, last paragraph) which represents DNA including a predetermined gene, as stated in instant claim 5 and (=first portion) in instant claim 15. Figure 2 shows the CS gene with CS repeats (=gene portion) along with the 5' flanking region wherein the flanking region represents a portion which is other than the gene portion, as stated in instant claim 5 and (=second portion) in instant claim 15. Figure 1 shows two types of tandem repeat primers with TAG sequences bound to the genomic sequence. It is noted that Merriam-Webster online dictionary defines "embed" as to make something an integral part of. Arnot et al. disclose

hybridizing probes in a strategy to extract information on sequence variation called DNA barcodes to identify parasite stocks and lineages (abstract) while Figure 2 shows using a CS region flanking primer as well as a TAGed Type I complement primer wherein the primers represent not naturally occurring nucleotide sequences and the flanking primer represents a sequence embedded in portion other than said gene portion which identifies source of predetermined gene, as stated in instant claims 5, 8, 11, 15, and 27. Arnot et al. disclose designing specific primers (page 16, col. 1, second paragraph; page 16, col. 2, last paragraph to page 17, col. 1, first paragraph) wherein the primers represent intentionally designed special sequences, as stated in instant claim 8. Arnot et al. disclose amplifying DNA fragments using the flanking and TAG complement primer (page 18, col. 1, first paragraph). Table 1 (and its caption) lists interspersion patterns of variant tandem repeats hybridized to primers and transformed into barcodes for CS genes of 20 isolates of P. falciparum which represents a plurality of sequences embedded at predetermined locations (as stated in instant claims 9 and 19) and Figures 2 and 3 show a plurality of sequences having a plurality of types of patterns embedded at predetermined locations of DNA, as stated in instant claims 10 and 18. The different primers and sequence lengths (i.e. page 16, last paragraph to page 17, first paragraph; Figure 2c) represent different nucleotide sequences, as stated in instant claim 20. Arnot et al. disclose DNA probes that hybridize to many dispersed mini-satellite loci simultaneously to produce an individual specific genome fingerprint (page 15, col. 1, first paragraph). Arnot et al. disclose the ability to trace malarial infection with the CS locus barcode to identify routes of infection and persistent foci and unusually infectious individuals (page 23, col. 1, last paragraph) which represents a value-added gene provided by selective breeding wherein the ability to trace

infection routes represent value of the gene, as stated in instant claim 17. Arnot et al. disclose the unique "barcodes" among various isolates of P. falciparum in Table 1 and identifying lineages from these barcodes (abstract) which represents at least one nucleotide sequence which is copy tolerant, as stated in instant claim 21. Figure 2c-d shows a TAGed Type I complement primer randomly attached to one of the Type I CS repeats which is amplified also using the flanking primer, which represents a sequence embedded at a random location, as stated in instant claim 22. Arnot et al. disclose designing specific primers (page 16, col. 1, second paragraph) which represents a sequence not naturally generated through gene mutation, as stated in instant claim 23. Arnot et al. disclose producing radiolabelled marker fragments by 3' end labeling a MspI digest of pBR322 using [32P]dCTP and the Klenow enzyme (page 17, col. 1, second paragraph) which represents one of a restrictive enzyme identification sequence and a promoter, as stated in instant claim 24. Arnot et al. disclose using a TAG sequence on the 5'end of primers that are complementary to the tandem repeats of the genomic sequence (Figure 1) as well as results using 32P-labelled PCR products (Figure 3) which represents at least one nucleotide sequence is detectable using a nucleotide sequence that is complementary to said at least one nucleotide sequence, as stated in instant claim 25. Figure 2 shows that Type I CS repeats occur in certain predetermined locations, including the flanking primer embedded in its specific location, as stated in instant claim 26. Table 1 shows patterns of variant tandem repeats with barcoding results, which represents a watermark sequence, as stated in instant claim 30. Arnot et al. disclose the CS gene region and flanking region (Figure 2) as well as genomic sequences with unexpressed tandemly repeated DNA sequences (abstract) which represents a gene portion

transcribed into RNA and an "other" portion not transcribed into RNA, as stated in instant claim 34.

Thus, Arnot et al. anticipate the limitations in instant claims 5, 8-11, 15, 17-27, 30, and 34.

#### (10) Response to Arguments

# 35 USC 112, 1st paragraph rejection

Appellants state various case law and that MPEP 2163 states that a patent specification need only describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. While this statement is true, it is noted in the NEW MATTER rejection that "genetic information" (as mentioned by Appellants on pages 12-13 of the application) and "protein code sequence and its transcription code information" (amended claim limitation) differ in scope. It is noted, as set forth above, that the specification does provide support for a "gene portion" which comprises a protein code sequence and transcription control; however, this is not support for a portion which is OTHER than a "gene portion" NOT comprising protein code or transcription control elements. Therefore, the originally filed disclosure does not provide support for the newly recited negative limitation of: "a portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence". Appellants argue that it was completely unreasonable to suggest that the specification does not describe the claimed invention of instant claim 32 in sufficient detail. This statement is found unpersuasive as the Appellants fail to point to specific written support in the

originally filed application for the negative limitation now recited for the "portion" which is NOT a gene portion. Appellants' arguments regarding alleged written support on pages 12-13 are unpersuasive for the reasons already addressed above.

Page 13

# 35 USC 112, 2<sup>nd</sup> paragraph rejection

Appellants summarize MPEP 2173.02 and various case law. Appellants submit that the phrase "intentionally designed" is used in claim 8 with the phrase "not naturally occurring" to distinguish the "at least one special sequence" from a naturally occurring sequence in DNA. This statement is found moot and unpersuasive as it is noted that claim 8 reads on living matter containing DNA comprising sequences which do not "naturally occur" within that organism's DNA (see 35 USC 101 rejection) and does not address the unclarity of the rejected phrase. Appellants argue that a skilled artisan would consider the phrase "not naturally occurring in said DNA and that is intentionally designed" to mean a sequence which may be intentionally designed by man, as opposed to a naturally occurring sequence in DNA. This statement is found unpersuasive as Appellants are arguing limitations that are not present in the claims, and the specification does not provide a limiting definition for "not naturally occurring". Appellants argue that the term (assumed to be "intentionally designed") is used to describe "at least one special sequence" that includes "source identification information", such as a watermark sequence. This statement and further statements regarding watermarks are found unpersuasive as it is not clear how these statements address the vague and indefinite issue of the rejected phrase.

#### 35 USC 102(b) rejection as anticipated by Lizardi (US 5,854,033)

Appellants summarize the rejection.

## 1. Independent claim 5

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach "a nucleotide sequence which is not naturally occurring in said DNA and which is embedded in said portion which is other than said gene portion, and comprises source identification information which identifies a source of said predetermined gene in said gene portion". This statement is found unpersuasive as Lizardi discloses detecting mutations in target sequence genes, for example the identified gene responsible for Huntington's chorea by designing an open circle probe (col. 22, lines 20-37), Figure 1 shows a open circle probe hybridized to a target sequence, and Figure 5 shows an open circle probe with detection tags which represents a first gene portion including a predetermined gene for Huntington's chorea, a second portion which is other than said gene portion (=probe), and a not naturally occurring nucleotide sequence (=detection tag) which is embedded in portion other than said gene portion with source identification information of said predetermined gene. as stated in instant claims 5, 8, 11, 12, 15, and 27. Appellants argue that the claimed invention helps to prevent legal copying of genetic information which is not a feature taught by Lizardi. This statement is moot as the instant claims do not recite such a limitation. Appellants argue that the purpose of Lizardi is to detect specific nucleic acids in a sample with high specificity and sensitivity. This statement is moot as the purpose need not be the same as that of the instant

invention. Appellants argue that Lizardi has nothing to do with identifying a source of genetic information. This statement is found unpersuasive as detecting mutations in a target sequence gene, such as the identified gene responsible for Huntington's chorea (col. 22, lines 20-37) clearly represents identifying a source of genetic information. Appellants summarize Lizardi's invention. Appellants argue that the Examiner surprisingly attempts to equate the gene for Huntington's chorea for the instantly claimed "predetermined gene", the probe for the instantly claimed "a second portion which is other than said gene portion", and detection tag for the "nucleotide sequence which is not naturally occurring in said DNA". This representation of the mentioned claimed language is acknowledged. Appellants argue that this representation confusingly alleges that Lizardi discloses DNA that includes 1) a gene portion including Huntington's chorea gene, and 2) the open circle probe (OCP) while Lizardi does not teach DNA that includes the gene for Huntington's chorea and the OCP. This statement is found unpersuasive as Lizardi discloses these limitations in col. 22, lines 20-37, as well as Figures 1 and 5 and the abstract. Appellants argue that the "nucleotide sequence which is not naturally occurring in said DNA" may include a watermark sequence. It is noted that claim 5 does not recite any watermark limitation; however, claim 30 does. Lizardi discloses the detection tag portions of the open circle probe may have 60 tag portions or less with same or different sequences which can be any length that supports specific and stable hybridization between tags and the probes (col. 7, lines 6-31), which represents embedding at random locations as well as watermark (=specific sequences), as stated in instant claims 22 and 30. Appellants argue that Lizardi does not teach that the "detection tag" may identify the source of the Huntington's chorea gene or that the detection tag may be used to identify ACME Corporation as the source of

Page 15

Application/Control Number: 09/870,009 Page 16

Art Unit: 1631

the Huntington chorea gene. This statement is found unpersuasive as a detection tag detects, or identifies, the gene, which represents identifying a source of the gene. Furthermore, the arguments regarding identifying the ACME Corporation (e.g. a company or specific laboratory "source") are most as the instant claims fail to recite such a limitation.

#### 2. Independent claim 8

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach "wherein said at least one special sequence comprises source identification information which identifies the source of a predetermined gene which is included in a gene portion of said DNA". This statement is found unpersuasive for the same reasons as those set forth above for claim 5. In addition, Lizardi discloses DNA ligation which circularizes a specially designed nucleic acid probe used to detect the presence of specific nucleic acids in a sample (abstract) containing the detection tags (Figure 5) which represents a special sequence that is intentionally designed and included as part of the nucleotide sequence, as stated in instant claim 8. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper. Appellants note that the features of claim 8 are similar to the features of instant claim 5 and their arguments are incorporated by reference. It is noted that the arguments to instant claim 5 were deemed unpersuasive for the reasons give above.

Application/Control Number: 09/870,009 Page 17

Art Unit: 1631

# 3. Independent claim 11

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach "source identification information which identifies a source of a predetermined gene in a gene portion of said DNA". This statement is found unpersuasive for the same reasons as those set forth above for claim 5. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper. Appellants note that the features of claim 11 are similar to the features of instant claim 5 and their arguments are incorporated by reference. It is noted that the arguments to instant claim 5 were deemed unpersuasive for the reasons give above.

#### 4. Independent claim 12

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach "a nucleotide sequence which is not naturally occurring in said DNA and which is embedded in said portion which is other than said gene portion, and comprises source identification information which identifies a source of said predetermined gene in said gene portion". This statement is found unpersuasive for the same reasons as those set forth above for claim 5. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper. Appellants note that the features of claim 12 are similar to the features of instant claim 5 and their arguments

are incorporated by reference. It is noted that the arguments to instant claim 5 were deemed unpersuasive for the reasons give above.

Page 18

#### 5. Independent claim 15

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the last three lines of instant claim 15. This statement is found unpersuasive for the same reasons as those set forth above for claim 5. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper. Appellants note that the features of claim 15 are similar to the features of instant claim 5 and their arguments are incorporated by reference. It is noted that the arguments to instant claim 5 were deemed unpersuasive for the reasons give above.

#### 6. Dependent claim 9

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 9. This statement is found unpersuasive as Figure 5 shows multiple detection tags, a primer complement, a promoter, and target probes which represent at least one special sequence with a plurality of sequences having a plurality of types of patterns (=different sequence patterns) embedded at predetermined locations of DNA, as stated in instant claims 9, 10, and 18-20. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

Application/Control Number: 09/870,009

Art Unit: 1631

7. Dependent claim 10

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This

statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach the limitations of instant claim 10. This statement is

Page 19

found unpersuasive as Figure 5 shows multiple detection tags, a primer complement, a promoter,

and target probes which represent at least one special sequence with a plurality of sequences

having a plurality of types of patterns (=different sequence patterns) embedded at predetermined

locations of DNA, as stated in instant claims 9, 10, and 18-20. Appellants fail to provide reasons

why the examiner's statements regarding Lizardi's patent would be considered improper.

8. Dependent claim 17

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This

statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach the limitations of instant claim 17. This statement is

found unpersuasive as Lizardi discloses detecting various mutant genes (Examples 2 and 3)

which represent a value-added gene that is provided by gene manipulation, as stated in instant

claim 17. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's

patent would be considered improper.

# 9. Dependent claim 18

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 18. This statement is found unpersuasive as Figure 5 shows multiple detection tags, a primer complement, a promoter, and target probes which represent at least one special sequence with a plurality of sequences having a plurality of types of patterns (=different sequence patterns) embedded at predetermined locations of DNA, as stated in instant claims 9, 10, and 18-20. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 10. Dependent claim 19

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 19. This statement is found unpersuasive as Figure 5 shows multiple detection tags, a primer complement, a promoter, and target probes which represent at least one special sequence with a plurality of sequences having a plurality of types of patterns (=different sequence patterns) embedded at predetermined locations of DNA, as stated in instant claims 9, 10, and 18-20. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

# 11. Dependent claim 20

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 20. This statement is found unpersuasive as Figure 5 shows multiple detection tags, a primer complement, a promoter, and target probes which represent at least one special sequence with a plurality of sequences having a plurality of types of patterns (=different sequence patterns) embedded at predetermined locations of DNA, as stated in instant claims 9, 10, and 18-20. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

## 12. Dependent claim 21

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 21. This statement is found unpersuasive as Lizardi discloses copies of the open circle probe in Figure 11b which represents copy tolerance, as stated in instant claim 21. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 13. Dependent claim 22

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 22. This statement is

found unpersuasive as Lizardi discloses the detection tag portions of the open circle probe may have 60 tag portions or less with same or different sequences which can be any length that supports specific and stable hybridization between tags and the probes (col. 7, lines 6-31) which represents embedding at random locations as well as watermark (=specific sequences), as stated in instant claims 22 and 30. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 14. Dependent claim 23

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 23. This statement is found unpersuasive as the detection portion of the open circle probe is separate from the target sequence containing the gene (Figure 5 and 8) which represents at least one nucleotide sequence which is not naturally generated through gene mutation, as stated in instant claim 23. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 15. Dependent claim 24

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 24. This statement is found unpersuasive as Lizardi discloses using enzyme-linked detection systems (abstract) and

Figure 5 shows the promoter of the open circle probe, as stated in instant claim 24. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 16. Dependent claim 25

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 25. This statement is found unpersuasive as Lizardi discloses if any target sequences are present, then the open circle probe ligates to it and detection tags allow for detection (col. 22, lines 37-49) which represents detecting a complementary sequence, as stated in instant claim 25. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 17. Dependent claim 26

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 26. This statement is found unpersuasive as Figure 5 gives an example of detection tags being embedded at predetermined locations, as stated in instant claim 26. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 18. Dependent claim 27

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach the limitations of instant claim 27. This statement is found unpersuasive as Lizardi discloses detecting mutations in target sequence genes, for example the identified gene responsible for Huntington's chorea by designing an open circle probe (col. 22, lines 20-37), Figure 1 shows a open circle probe hybridized to a target sequence, and Figure 5 shows an open circle probe with detection tags which represents a first gene portion including a predetermined gene for Huntington's chorea, a second portion which is other than said gene portion (=probe), and a not naturally occurring nucleotide sequence (=detection tag) which is embedded in portion other than said gene portion with source identification information of said predetermined gene, as stated in instant claims 5, 8, 11, 12, 15, and 27. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 19. Dependent claim 30

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach the limitations of instant claim 30. This statement is found unpersuasive as Lizardi discloses the detection tag portions of the open circle probe may have 60 tag portions or less with same or different sequences which can be any length that supports specific and stable hybridization between tags and the probes (col. 7, lines 6-31), which

represents embedding at random locations as well as watermark (=specific sequences), as stated in instant claims 22 and 30. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 20. Dependent claim 31

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 31. This statement is found unpersuasive as the genes in Examples 2 and 3 represent protein code sequence and Figure 8 shows transcriptional initiation sites, as stated in instant claim 31. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 21. Dependent claim 32

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Lizardi does not teach the limitations of instant claim 32. This statement is found unpersuasive as Figure 5 shows detection tag portions which represent a portion which is other than said gene portion that does not store protein code sequence and transcriptional control information, as stated in instant claim 32. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

Application/Control Number: 09/870,009 Page 26

Art Unit: 1631

#### 22. Dependent claim 33

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach the limitations of instant claim 33. This statement is found unpersuasive as Lizardi discloses using oligonucleotides for wild type and mutant gene detection via ligation (col. 36, line 19 to col. 37, line 20 and col. 38, line 48 to col. 39, line 67) which represents producing a gene by artificial, intentional manipulation, as stated in instant claim 33. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

#### 23. Dependent claim 34

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Lizardi does not teach the limitations of instant claim 34. This statement is found unpersuasive as Figure 10 shows amplified RNA which represents a gene portion transcribed into RNA and a portion other than said gene portion which is not transcribed, as stated in instant claim 34. Appellants fail to provide reasons why the examiner's statements regarding Lizardi's patent would be considered improper.

## 35 USC 102(b) rejection as anticipated by Arnot et al.

Appellants summarize the rejection.

### 1. Independent claim 5

Appellants summarize Arnot et al. Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Arnot et al. do not teach "a nucleotide sequence which is not naturally occurring in said DNA and which is embedded in said portion which is other than said gene portion, and comprises source identification information which identifies a source of said predetermined gene in said gene portion". This statement is found unpersuasive as Arnot et al. disclose genomic DNA including the CS gene of Plasmodium falciparum (abstract and page 17, col. 1, last paragraph), which represents DNA including a predetermined gene. Figure 2 shows the CS gene with CS repeats (=gene portion) along with the 5' flanking region wherein the flanking region represents a portion which is other than the gene portion, as stated in instant claim 5. Figure 1 shows two types of tandem repeat primers with TAG sequences bound to the genomic sequence. It is noted that Merriam-Webster online dictionary defines "embed" as to make something an integral part of. Arnot et al. disclose hybridizing probes in a strategy to extract information on sequence variation called DNA barcodes to identify parasite stocks and lineages (abstract) while Figure 2 shows using a CS region flanking primer as well as a TAGed Type I complement primer wherein the primers represent not naturally occurring nucleotide sequences and the flanking primer represents a sequence embedded in portion other than said gene portion which identifies source of predetermined gene, as stated in instant claim 5. Appellants argue that the claimed invention helps to prevent legal copying of genetic information

which is not a feature taught by Arnot et al. This statement is moot as the instant claims do not recite such a limitation. Appellants argue that the purpose of Arnot et al. is to identify lineages of drug-resistant parasites. This statement is moot as the purpose need not be the same as that of the instant invention. Appellants argue that Arnot et al. has nothing to do with DNA that includes source identification information. This statement is found unpersuasive as Arnot et al. disclose this limitation as already addressed above. Appellants argue that the Examiner surprisingly attempts to equate the CS gene to the instantly claimed "predetermined gene", the CS repeats to the instantly claimed "gene portion", a flanking region to the "portion which is other than said gene portion", and a CS region flanking region to the "nucleotide sequence which is not naturally occurring in said DNA". This representation of the mentioned claimed language is acknowledged. Appellants argue that Arnot et al. do not teach a "portion which is other than said gene portion". This statement is found unpersuasive as Arnot et al. disclose hybridizing probes in a strategy to extract information on sequence variation called DNA barcodes to identify parasite stocks and lineages (abstract) while Figure 2 shows using a CS region flanking primer as well as a TAGed Type I complement primer wherein the primers represent not naturally occurring nucleotide sequences and the flanking primer represents a sequence embedded in a portion other than said gene portion which identifies source of predetermined gene. Appellants argue that the claimed nucleotide sequence is embedded in a portion which is other than said gene portion. It is noted that Arnot et al. also disclose this limitation, as addressed in the preceding sentence. Appellants argue that the embedded nucleotide sequence may be referred to as a watermark sequence and summarize the invention. It is noted that claim 5 does not recite any watermark limitation; however, claim 30 does. Table 1 in Arnot et al. shows patterns of

variant tandem repeats with barcoding results which represents a watermark sequence, as stated in instant claim 30. Appellants argue that if the watermark sequence is detected in the DNA, it can be ascertained that the gene of the organism is a copy of DNA wherein the watermark was previously embedded. This statement is moot as claim 5 does not mention such limitations, and while claim 30 mentions a watermark sequence, it fails to recite any of these other limitations argued by Appellants. Appellants argue that the term "embedded" as described by Arnot et al. is contrary to the use of the term in the present application. This statement is found unpersuasive as the instant application fails to provide a clear definition of the term. Therefore, the term has been broadly and reasonably interpreted to have its "normal and customary" meaning. It is noted that Merriam-Webster online dictionary defines "embed" as to make something an integral part of. Appellants argue that Arnot et al. do not suggest that the flanking region includes "source identification information". This statement is found unpersuasive as Arnot et al. disclose hybridizing probes in a strategy to extract information on sequence variation called DNA barcodes to identify parasite stocks and lineages (abstract) while Figure 2 shows using a CS region flanking primer as well as a TAGed Type I complement primer wherein the primers represent not naturally occurring nucleotide sequences and the flanking primer represents a sequence embedded in portion other than said gene portion which identifies a source of a predetermined gene.

#### 2. Independent claim 8

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. do not teach "wherein said at least one special sequence comprises source identification information which identifies the source of a predetermined gene which is included in a gene portion of said DNA". This statement is found unpersuasive for the same reasons as those set forth above for claim 5. In addition, Arnot et al. disclose designing specific primers (page 16, col. 1, second paragraph; page 16, col. 2, last paragraph to page 17, col. 1, first paragraph) wherein the primers represent intentionally designed special sequence, as stated in instant claim 8. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper. Appellants note that the features of claim 8 are similar to the features of instant claim 5 and their arguments are incorporated by reference. It is noted that the arguments to instant claim 5 were deemed unpersuasive for the reasons give above.

### 3. Independent claim 11

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach "source identification information which identifies a source of a predetermined gene in a gene portion of said DNA". This statement is found unpersuasive for the same reasons as those set forth above for claim 5. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

Appellants note that the features of claim 11 are similar to the features of instant claim 5 and their arguments are incorporated by reference. It is noted that the arguments to instant claim 5 were deemed unpersuasive for the reasons give above.

# 4. Independent claim 15

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the last three lines of instant claim 15. This statement is found unpersuasive for the same reasons as those set forth above for claim 5.

Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper. Appellants note that the features of claim 15 are similar to the features of instant claim 5 and their arguments are incorporated by reference. It is noted that the arguments to instant claim 5 were deemed unpersuasive for the reasons give above.

### 5. Dependent claim 9

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement if found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 9. This statement is found unpersuasive as Table 1 (and its caption) lists interspersion patterns of variant tandem repeats hybridized to primers and transformed into barcodes for CS genes of 20 isolates of *P. falciparum* which represents a plurality of sequences embedded at predetermined locations. Appellants fail to argue why these statements regarding Arnot et al. would be considered improper.

## 6. Dependent claim 10

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. do not teach the limitations of instant claim 10. This statement is found unpersuasive as Table 1 (and its caption) lists interspersion patterns of variant tandem repeats hybridized to primers and transformed into barcodes for CS genes of 20 isolates of *P. falciparum*, which represents a plurality of sequences embedded at predetermined locations.

Further, Figures 2 and 3 show a plurality of sequences having a plurality of types of patterns embedded at predetermined locations of DNA. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

#### 7. Dependent claim 17

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 17. This statement is found unpersuasive as Arnot et al. disclose the ability to trace malarial infection with the CS locus barcode to identify routes of infection and persistent foci and unusually infectious individuals (page 23, col. 1, last paragraph) which represents a value-added gene provided by selective breeding wherein the ability to trace infection routes represent value of the gene, as stated in instant claim 17. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

#### 8. Dependent claim 18

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement sf found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 18. This statement is found unpersuasive as Table 1 (and its caption) lists interspersion patterns of variant tandem repeats hybridized to primers and transformed into barcodes for CS genes of 20 isolates of *P. falciparum* which represents a plurality of sequences embedded at predetermined locations and Figures 2 and 3 show a plurality of sequences having a plurality of types of patterns embedded at predetermined locations of DNA, as stated in instant claim 18. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

#### 9. Dependent claim 19

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 19. This statement is found unpersuasive as Table 1 (and its caption) lists interspersion patterns of variant tandem repeats hybridized to primers and transformed into barcodes for CS genes of 20 isolates of *P. falciparum* which represents a plurality of sequences embedded at predetermined locations (as stated in instant claim 19) and Figures 2 and 3 show a plurality of sequences having a plurality of types of patterns embedded at predetermined locations of DNA. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

Application/Control Number: 09/870,009 Page 34

Art Unit: 1631

10. Dependent claim 20

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 20. This statement is found unpersuasive as the different primers and sequence lengths (i.e. page 16, last paragraph to page 17, first paragraph; Figure 2c) represent different nucleotide sequences, as stated in instant claim 20. Appellants fail to argue why the examiner's statements regarding

11. Dependent claim 21

Arnot et al. would be considered improper.

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 21. This statement is found unpersuasive as Arnot et al. disclose the unique "barcodes" among various isolates of *P. falciparum* in Table 1 and identifying lineages from these barcodes (abstract) which represents at least one nucleotide sequence is copy tolerant, as stated in instant claim 21. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

12. Dependent claim 22

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Arnot et al. does not teach the limitations of instant claim 22. This statement is found unpersuasive as Figure 2c-d shows a TAGed Type I complement primer randomly attached to one of the Type I CS repeats which is amplified also using the flanking

primer which represents a sequence embedded at a random location, as stated in instant claim 22.

Appellants fail to argue why the examiner's statements regarding Arnot et al. would be

considered improper.

13. Dependent claim 23

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This

statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 23. This

statement is found unpersuasive as Arnot et al. disclose designing specific primers (page 16, col.

1, second paragraph) which represents a sequence not naturally generated through gene mutation.

as stated in instant claim 23. Appellants fail to argue why the examiner's statements regarding

Arnot et al. would be considered improper.

14. Dependent claim 24

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This

statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 24. This statement is found unpersuasive as Arnot et al. disclose producing radiolabelled marker fragments by 3' end labeling a MspI digest of pBR322 using [32P]dCTP and the Klenow enzyme (page 17, col. 1, second paragraph) which represents one of a restrictive enzyme identification sequence and a promoter, as stated in instant claim 24. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

# 15. Dependent claim 25

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. disclose using a TAG sequence on the 5'end of primers that are complementary to the tandem repeats of the genomic sequence (Figure 1) as well as results using 32P-labelled PCR products (Figure 3) which represents at least one nucleotide sequence is detectable using a nucleotide sequence that is complementary to said at least one nucleotide sequence, as stated in instant claim 25. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

#### 16. Dependent claim 26

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 26. This statement is found unpersuasive as Figure 2 shows that Type I CS repeats occur in certain

predetermined locations, including the flanking primer embedded in its specific location, as stated in instant claim 26. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

#### 17. Dependent claim 27

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Arnot et al. does not teach the limitations of instant claim 27. This statement is found unpersuasive for the same reasons as those set forth above for claim 5. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

#### 18. Dependent claim 30

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support. Appellants argue that Arnot et al. does not teach the limitations of instant claim 30. This statement is found unpersuasive as Table 1 shows patterns of variant tandem repeats with barcoding results which represents a watermark sequence, as stated in instant claim 30. Appellants fail to argue why the examiner's statements regarding Arnot et al. would be considered improper.

Application/Control Number: 09/870,009 Page 38

Art Unit: 1631

19. Dependent claim 34

Appellants argue that the Examiner's position is flawed as a matter of fact and law. This statement is found unpersuasive as it is a conclusory statement without factual support.

Appellants argue that Arnot et al. does not teach the limitations of instant claim 34. This statement is found unpersuasive as Arnot et al. disclose the CS gene region and flanking region (Figure 2) as well as genomic sequences with unexpressed tandemly repeated DNA sequences (abstract) which represents gene portion transcribed into RNA and other said portion not transcribed into RNA, as stated in instant claim 34. Appellants fail to argue why the examiner's

In summary, Appellants' arguments are deemed unpersuasive for the reasons given above.

(11) Related Proceeding(s) Appendix

statements regarding Arnot et al. would be considered improper.

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Conclusion

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above.

Accordingly, appellant must within TWO MONTHS from the date of this answer exercise one

of the following two options to avoid *sua sponte* dismissal of the appeal as to the claims subject to the new ground of rejection:

- (1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.
- (2) Maintain appeal. Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28,

1993) (See 37 CFR §1.6(d)). The Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Yolanda Chadwick whose telephone number is (571) 272-0514.

Respectfully submitted,

Examiner C. Smith (AU 1631)

August 9, 2006

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Conferees:

Andrew Wang, SPE AU 1631

Ram Shukla, SPE AU 1632

Marjorie Moran, Primary Examiner AU 1631

MARJORIE A. MORAN PRIMARY EXAMINER

8131/02

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